Meeting of the
Pharmacy and Therapeutics Committee
July 30, 2003
Minutes
Final

Members Present:
Randy Axelrod
Gill Abernathy
Roy Beveridge (via phone)
Eleanor S. (Sue) Cantrell
Avtar Dhillion
Mariann Johnson

Mark Oley
Christine Tully
Renita Warren

Absent:
Arthur Garson, Jr.
James Reinhard
Mark Szalwinski

DMAS Staff:
Patrick Finnerty, Director DMAS
Cynthia Jones, Chief Deputy Director
Cheryl Roberts, Deputy Director of Programs and Operations
Manju Ganeriwala, Deputy Director of Finance and Administration
Paige Fitzgerald, Counsel to the Board
Adrienne Fegans, Program Administration Specialist
Bryan Tomlinson, Director, Division of Health Care Services
Craig Markva, Acting Director, Office of Communications & Legislative Affairs

First Health Staff:
Ed Borovatz, Vice President of Pharmacy Benefit Services
Frank Shelp, MD, Medical Director
Cathy England, RPh, Director of Clinical Operations
Debbie Stephens, RPh, VA PDL Implementation Project Director
Donna Johnson, RPh, VA Clinical Account Manager
Chuck Baker, RPh, VA PDL Clinical Manager
Annette Paul, RPh, Clinical Manager
Sandy Kapur, PharmD, Clinical Support
Doug Adams, PharmD, Rebate Support
Carol Perkins, PharmD, Clinical Support

Guests:
Manikoth Kurup, MD, Member, Board of Medical Assistance Services
Wayne Turnage, Deputy Secretary of Health and Human Resources
54 representatives from pharmaceutical companies, providers, advocates, associations, etc.

Welcome and Introductions

Director Patrick Finnerty welcomed everyone to the second meeting of the P&T Committee and asked the members of the Committee to introduce themselves. Mr. Finnerty announced that First Health Services will be the administrator of the Preferred Drug List and Prior Authorization Programs. He introduced Ed Borovatz, Vice President of the Pharmacy Division at First Health. Mr. Borovatz thanked Mr. Finnerty for the privilege and opportunity to work with the Commonwealth on this program. He asked the members of the First Health staff to introduce themselves and provide information about their role in this program.

Mr. Finnerty announced that Chairman Axelrod spoke to a subcommittee of the Joint Commission on Health Care about the P&T Committee and the PDL process on July 8, 2003. Mr. Finnerty also stated that Cindi Jones, Chief Deputy Director, presented an overview of the PDL program to the Health and Human Resources Subcommittee of the House Appropriations Committee on July 11, 2003.

Mr. Finnerty provided an overview of today's meeting agenda to include the review of the minutes of the previous meeting, comments from Chairman Axelrod, an overview of the role of

First Health Services in the Program, clinical review of four drug classes and drug specific comments from interested parties.

Acceptance of Minutes from June 18th meeting

Chairman Axelrod asked the Committee if they had any corrections, additions or deletions to the minutes of the June 18th meeting. The motion was made and seconded to accept the minutes of the meeting as prepared.

Comments from the Chairperson

Chairman Axelrod said that at the last meeting numerous comments were made that showed the level of public concern about the process of creating a PDL. There was a great deal of anxiety from the subspecialties, for example, mental health, respiratory and allergic disease. The Committee recognizes the high level of anxiety surrounding the process and the importance of what needs to be done. Chairman Axelrod stated that the process will involve the review of therapeutic classes of medications and sometimes only the subsets of the therapeutic classes. This review process will focus on two distinct issues:

1. To determine if the therapeutic class or subclass is eligible for the PDL process. The Committee will have to determine if the medications in the class have distinct, succinct mechanisms of therapeutic modality and outcomes that would not allow for a class effect in this category of drugs. If so, this class would not be eligible for the PDL. However, if the majority of the drugs in a therapeutic class have similar pharmacokinetics and therapeutic outcomes then a class effect exists and the class will be eligible for the PDL process.
2. Revalidation of the class after the contractual process has been performed by First Health Services. The Committee will decide if any further clinical considerations to chosen drugs in the class are needed, such as additional prior authorization criteria.

Chairman Axelrod described the format of this process for the meetings. He will ask pre-identified interested parties to speak to the Committee at the beginning of the discussion of each therapeutic class or subclass. These presentations will be limited to clinical data only. Afterward, a member of the Committee will present information specific to that class. Then the Committee will make a determination about the eligibility of the class taking into consideration both written and oral materials.

Introduction and Overview by First Health Services

Annette Paul stated that First Health Services is available to support the work of the Committee and will provide information, as needed, about the implementation process. Additionally, First Health will provide any clinical information requested by the Committee to aid them in their discussions of the therapeutic classes.

Drug Class Discussions

The following drug classes were reviewed

- **Proton Pump Inhibitors (PPI)**
- **H2 Receptor Antagonists (H2RA)**
- **Antihistamines**
- **Nasal Steroids**

Proton Pump Inhibitors (PPI) and H2 Receptor Antagonists (H2RA)

Public Comments (Note: The copies of the handouts presented to the Committee are included at the end of the minutes):

1. Paul Prince (Astra Zeneca) – Mr. Prince presented several clinical evidence-based studies demonstrating the efficacy of esomeprazole (Nexium®). He stated that the conventional esophageal healing in gastroesophageal reflux disease (GERD) with proton pump inhibitors (PPIs) is 85%. According to Mr. Prince, esomeprazole can fill the gap between other products and complete esophageal healing. Lastly, Mr. Prince presented studies that show the effectiveness of esomeprazole in the maintenance of erosive esophagitis to be in the range of 93 to 95%.

2. Kristen Mack (Janssen) – Ms. Mack stated that all proton pump inhibitors are effective. However, she wished to point out some of the differences between rabeprazole (Aciphex®) and the other PPIs. Ms. Mack presented studies that showed the effectiveness of rabeprazole in controlling gastric pH with just one dose. The studies also showed that rabeprazole has a reduced adverse effect profile compared to the other PPIs. The most commonly reported adverse effect was headache, while the other PPIs most commonly reported abdominal pain and diarrhea. Ms. Mack also presented studies that showed the cost effectiveness of rabeprazole compared to lansoprazole and omeprazole based on the daily average consumption (DACON) of each product. These studies showed that, overall, rabeprazole is the most cost effective of the PPIs, especially at controlling GERD.

3. Tanner Odum (Tap) – Mr. Odum agreed with the other presenters that PPIs are all very effective. He discussed three key points that he wished the Committee to consider about lansoprazole (Prevacid®):
   a. Prevacid® leads the PPI class with the number of FDA approved indications. Prevacid® has thirteen approved indications. The two most recent approved indications are for pediatric GERD and erosive esophagitis.
   b. Prevacid® leads the market in the number of alternative dosage forms. The currently available dosage forms include – capsules (which can be opened and the contents sprinkled into soft food and beverages), a suspension and dissolvable tablets.
   c. Prevacid® is currently the PPI of choice among the Virginia Medicaid providers based on the number of prescriptions dispensed. This point was confirmed by First Health Services.

Presentation by Committee Member Mark Oley

Mr. Oley opened his presentation by saying that he wanted to focus on whether the PPIs are eligible for the PDL. He listed the five PPIs - Prilosec®, Aciphex®, Protonix® Nexium, and Prevacid®. Of these, Prilosec® is the only one available as a generic. And this generic product is not priced much less than the brand because it is made by only one manufacturer. Mr. Oley stated that
clinical studies show that all five products have equal effectiveness. There are minimal differences between the PPIs using the secondary endpoints of in vitro pH and acid suppression. Additionally, Mr. Oley noted that there are some differences in formulation. Protonix® is the only one available in an injectable formulation. Prevacid® is available as granules for suspension and omeprazole capsules may be compounded with bicarbonate or the capsules may be opened and the contents sprinkled in applesauce. Overall, Mr. Oley concluded that the PPIs exhibit a class effect and are therefore eligible for the PDL process.

Mr. Oley continued his presentation with the H2 Receptor Antagonists – Tagamet®, Pepcid®, Zantac®, and Axid®. All of these products are available generically. All are indicated for the treatment and maintenance of duodenal and gastric ulcers as well as the treatment of GERD. All are most effective when taken at bedtime to reduce nocturnal acid secretion. The adverse events are very similar among these agents with constipation and diarrhea being the most common. He further pointed out that cimetidine has the most significant drug interaction profile due to its involvement with the cytochrome P450 pathway. Overall, Mr. Oley concluded that the H2RAs exhibit a class effect and are therefore eligible for the PDL process. Both Mr. Oley and Chairman Axelrod agreed that these agents should be considered for a mandatory generic program.

Chairman Axelrod asked the Committee if they considered these classes PDL eligible at which point they will be turned over to First Health Services for contractual purposes. Dr. Beveridge expressed concern that Tagamet® would not be available for use in liver patients. Both Chairman Axelrod and Mr. Finnerty assured Dr. Beveridge that drugs that are not included on the PDL will be available through the prior authorization (PA) process. Ms. Abernathy expressed concern about the potential drug interactions involving cimetidine. And lastly, Dr. Tully is concerned about the mental status changes that occur in her elderly patients as a result of cimetidine therapy. She wants to make sure that there will be other agents available to choose from so that she can avoid cimetidine use in the elderly.

Chairman Axelrod asked for the motion to include PPIs and H2RAs as a class effect and therefore eligible for the PDL process. The motion was made and seconded to include these agents in the PDL process. The vote was unanimous.

Antihistamines

Public Comments (Note: The copies of the handouts presented to the Committee are included at the end of the minutes):

1. Bruce Knight (Aventis) – Mr. Knight highlighted the Howard Study to demonstrate that fexofenadine (Allegra®) is equal to cetirizine in effectiveness. However, fexofenadine causes less drowsiness than cetirizine. Mr. Knight stated that all of the non-sedating antihistamines are effective. Ms. Warren asked if there were any pediatric studies with fexofenadine in children under six years old. Mr. Knight stated that currently there were no such studies with fexofenadine in progress at this time.

2. Barry Tucker (Schering) – Mr. Tucker agrees that all of the second-generation antihistamines are equal in effectiveness and side effect profiles. However, he feels that desloratadine (Clarinex®) is more potent than the others and therefore offers the advantage of lower dosing frequency.

3. Marylou Hayden, FNP (Virginia Adult and Pediatric Allergy and Asthma Association) – Ms. Hayden spoke as a patient advocate expressing concerns about the limited access to prescription antihistamines and nasal steroids in patients with allergies.

Presentation by Committee Member Mark Oley

Mr. Oley listed the non-sedating antihistamines in this class – Allegra®, Claritin®, Zyrtec® and Clarinex®. In addition, there are combination products containing these antihistamines and psuedoephedrine – Allegra-D®, Claritin-D® and Zyrtec-D®. Mr. Oley described some of the differences and similarities of the non-sedating antihistamines. He stated that loratadine is the only one of these available in a generic formulation (Claritin® and Alavert®). Zyrtec is actually classified as a less-sedating antihistamine and not a non-sedating as are Allegra® and Claritin®. All of these agents are indicated for seasonal allergic rhinitis and chronic idiopathic uticaria. Mr. Oley cited a comprehensive evidence-based review by the Agency for Healthcare Research and Quality published in May 2002. This review did not identify any one non-sedating antihistamine as more effective for allergic rhinitis. Furthermore, Mr. Oley stated that the non-sedating second-generation antihistamines are no more effective than the first generation antihistamines. However, the overall side (should this be side effect?) profile of the first generation antihistamines (e.g. sedation) is in most cases is unacceptable. Mr. Oley concluded that the second-generation non-sedating antihistamines do exhibit a class effect and should therefore be considered eligible for the PDL process.

Chairman Axelrod asked for the motion to include the non-sedating antihistamines in the PDL process. The motion was made and seconded. The vote was unanimous.

Nasal Steroids

Public Comments (Note: The copies of the handouts presented to the Committee are included at the end of the minutes):

1. Faith McKeon (AstraZeneca) – Ms. McKeon stated that all of the nasal steroids are effective within the therapeutic doses approved by the FDA. She said that the differences in the various formulations should be considered. For example, some products contain the preservative benzalkonium chloride. This ingredient can cause rebound congestion in up to 25% of patients. These patients will return to their physician complaining that their nasal steroid is not working. The physician may add an antihistamine to the treatment and thus drive up the healthcare costs, when simply switching to another nasal steroid product may be all that is needed.

2. Bruce Knight (Aventis) – Mr. Knight agrees that all of the nasal steroids are equally effective and extremely safe. He said the benzalkonium chloride (BKA) and many other preseveratives are found in many of the products, but that overall they are very well accepted and tolerated in the majority of patients. Also, Mr. Knight said that due to the low doses of steroids used in these products, they present few side effects.

3. Barry Tucker (Schering) – Mr. Tucker agrees that all of the nasal steroids are equally effective and safe. He cautioned, that as a whole, the safety corticosteroids becomes a concern. The advantage of the nasal products is that very little of the corticosteroid is absorbed systemically therefore, the typical side effects of the oral agents are rarely seen in these preparations. Mr. Tucker agrees that the exipients (preservatives, etc) in these preparations can potentially produce side effects in some patients. But he questions the amounts that would be needed to do this. In his product, flunisolide (Nasonex®), the rebound congestion due to BKC was found to occur in less than one percent of patients.

Presentation by Committee Member Mark Oley

Mr. Oley listed the nasal steroids available – Beconase AQ®, Rhinocort®, Nasalide®, Nasarel®, Flonase®, Nasonex® and Nasacort®. He stated that flucinolide is available over-the-counter (OTC) as Nasalide®. All are available in aqueous formulation. All are indicated for seasonal and perennial allergic rhinitis. All are FDA approved for children age six or greater. Flonase® is indicated for children age four and Nasonex® is indicated for children age two. All nasal steroids have similar adverse events and drug to drug interactions. Studies designed to demonstrate superiority of one agent over another have been inconsistent. Mr. Oley concluded that the nasal steroids should be included in the PDL process.

Mr. Oley noted that no matter what drugs are ultimately selected to be on the PDL, all other drugs will still be available to patients through a prior authorization process.

Chairman Axelrod thanked Mr. Oley for the time he spent in researching the drugs, preparing the discussion material and presenting it to the Committee. Chairman Axelrod asked the Committee

if there was any further discussion needed for the nasal steroids. He then asked for a motion the include these agents in the PDL process. The motion was made and seconded. The vote was unanimous

Next Meeting

Chairman Axelrod stated that the next meeting is tentatively scheduled for the afternoon of August 12, 2003. He hopes to confirm that within the next 24 hours. The subsequent meeting is scheduled for Wednesday, September 3, 2003. The drug classes to be reviewed have not yet been selected.

Chariman Axelrod asked the Committee for feedback concerning the meeting format and content, as well as, the format of the presentations.

Ms. Abernathy asked that findings of efficacy studies be included in the packet material. She also asked that the manufacturer name be included in the class review materials.

Dr. Tully asked that particular side effects for the elderly be included in the packet material.

Dr. Cantrell added that any notable side effects for a particular group of patients should be included. She said the FDA indications for each product should be included in the packet material as well.

Chairman Axelrod stated that while he agrees that it is important to include the indications, they should not dwell on them. This could make the process burdensome.

Chairman Axelrod reminded the Committee that there will be an Executive Session at the end of the next meeting.

Adjournment

Chairman Axelrod adjourned the meeting at 12:05 p.m.